

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images,
Please do not report the images to the
Image Problem Mailbox.


This Page Blank (uspic,



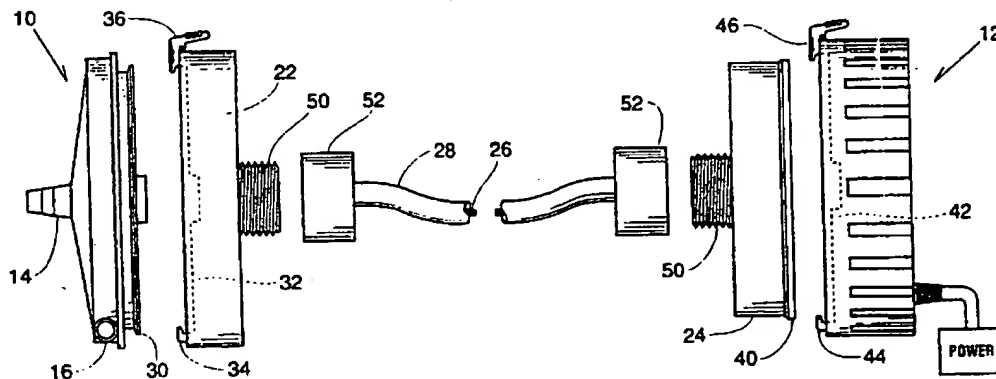
PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : F04B 17/00		A1	(11) International Publication Number: WO 00/19097
			(43) International Publication Date: 6 April 2000 (06.04.00)
(21) International Application Number: PCT/US99/22573		(81) Designated States: JP, European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).	
(22) International Filing Date: 30 September 1999 (30.09.99)		Published With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.	
(30) Priority Data: 09/164,407 30 September 1998 (30.09.98) US			
(71) Applicant: A-MED SYSTEMS, INC. [US/US]; 2491 Boatman Avenue, West Sacramento, CA 95691 (US).			
(72) Inventors: ABUL-HOSN, Walid, N.; 4625 Chicago Avenue, Fair Oaks, CA 95628 (US); KANZ, William, R.; 4695 Francis Court, Sacramento, CA 95822 (US); ZIEGLER, Roland; 3302 Kato Court, Cameron Park, CA 95682 (US).			
(74) Agents: RYAN, Daniel, D. et al.; 633 West Wisconsin Avenue, Milwaukee, WI 53203 (US).		 OCT 2 2000 RYAN KROMHOLZ & MANION S.C.	

(54) Title: BLOOD PUMP SYSTEM WITH MAGNETIC CABLE DRIVE



(57) Abstract

A blood pump system for use in CPB and other heart surgeries includes a magnetic cable drive (28) for remotely driving the blood pump. The magnetic cable drive is configured with magnetic couplings on each end (22, 24) such that the same motor (12) can be used to drive the pump (10) whether the pump is positioned directly on the motor or connected to the motor by the cable drive. This system allows the blood pump to be positioned within the sterile surgical field which advantageously reduces the priming volume of the pump.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

BLOOD PUMP SYSTEM WITH MAGNETIC CABLE DRIVE**CROSS-REFERENCE TO RELATED APPLICATIONS**

This application claims the benefit under Title 35, United States Code, §120 of United States Patent Application No. 09/164,407 filed on September 30, 1998 entitled "Blood Pump System with Magnetic Cable Drive."

BACKGROUND OF THE INVENTION**I. Field of the Invention**

The invention relates to a blood pump, and more particularly, the invention relates to a centrifugal blood pump system with a magnetic cable drive assembly for connecting and driving the blood pump with a remote motor.

II. Brief Description of the Related Art

Blood pumps used in surgical procedures such as cardiopulmonary bypass (CPB) and coronary artery bypass grafting (CABG) are single-use devices. These blood pumps are generally powered by a reusable motor which drives the pump through a magnetic coupling. However, the reusable motors are not sterilizable. Thus, the motor and attached pump are positioned outside the sterile surgical field at a location away from the patient. The disposable pump which is driven by the motor is connected to the patient by long lengths of tubing which transport the patient's blood to and from the blood pump. The long lengths of tubing increase the priming volume of the pump which is the amount

- 2 -

of the patient's blood and/or saline which must be drawn into the tubing and the pump to prime the pump before blood begins to be returned to the patient.

5 Long lengths of tubing connecting the pump to the patient also increase the amount of foreign material which comes into contact with the patient's blood, increasing trauma to the patient. A typical CPB circuit includes several feet of flexible tubing that the patient's blood flows through. In order to prevent blood clots, the
10 patient's blood is generally treated with Heparin. The use of Heparin is preferably minimized because Heparin prevents the blood from clotting.

An example of a prior art blood pump assembly including a disposable blood pump 10 and a reusable motor
15 12 is illustrated in FIGS. 1 and 2. The blood pump 10 has an axial blood inlet 14 and a tangential blood outlet 16.

An impeller within the fully enclosed and sterile blood pump 10 moves the blood from the inlet 14 to the outlet 16.

The pump 10 snaps onto the motor 12 and a magnetic
20 coupling between the pump 10 and the motor 12 is used to transmit the rotation of a motor drive shaft to the pump impeller. After use, the pump 10 is removed from the motor 12 and replaced with a new sterile blood pump 10 for the next patient. Due to the non-sterile condition of the
25 motor 12, the motor 12 and pump 10 must be positioned outside of the sterile surgical field.

In either stopped heart or beating heart surgery, it is desirable to minimize the priming volume of the blood pump by placing the pump as close as possible to the
30 surgical site and even within the chest cavity. By placing the pump close to or within the surgical field, the amount of saline required to prime the bypass circuit is reduced which reduces the likelihood that a transfusion will be required. Previous attempts to move the blood pump closer
35 to the patient have involved the use of a cable drive

- 3 -

system for the blood pump which allows the sterile pump to be located within the sterile surgical field while being driven from a remotely located motor. However, the use of a remotely located motor and cable drive system requires the use of one motor for directly driving the blood pump when the pump is positioned outside of the surgical field and requires a second motor with a cable drive system for driving the pump remotely when the pump is positioned inside the surgical field.

Accordingly, it would be desirable to provide a blood pump system which allows the same motor to drive the blood pump whether the blood pump is positioned within the surgical field close to the surgical site to minimize the priming volume of the pump or positioned outside of the surgical field in the conventional manner.

SUMMARY OF THE INVENTION

One aspect of the present invention involves providing a blood pump system. The blood pump system comprises a blood pump having an impeller for moving blood from an inlet to an outlet, and a magnetic coupler connected to the impeller. A motor is provided having a drive shaft and a magnetic coupler connected to the drive shaft, the magnetic coupler for magnetically driving the magnetic coupler of the blood pump. A drive coupler is provided having a flexible power transmission member extending between a first magnetic coupler and a second magnetic coupler. The first magnetic coupler is configured to be magnetically coupled to the magnetic coupler of the blood pump. The second magnetic coupler is configured to be magnetically coupled to the magnetic coupler of the motor.

In one embodiment of the blood pump system, a latching system is provided for connecting the pump to the motor such that the pump may be driven directly by the motor. The latching system is also for connecting the pump

- 4 -

to the drive coupler such that the pump may be driven remotely from the motor.

5 In one embodiment of the blood pump system, the latching system comprises an annular flange on the pump, an annular flange on the second magnetic coupler, engaging members on the first magnetic coupler for receiving the annular flange on the pump, and engaging members on the motor for receiving one of the annular flange on the pump and the annular flange on the second magnetic coupler.

10 In one embodiment of the blood pump system, the engaging members on the first magnetic coupler and on the motor include a tab and a lever arm.

15 In one embodiment of the blood pump system, the flexible power transmission member is removably coupled to at least one of the first magnetic coupler and the second magnetic coupler of the drive coupler.

In one embodiment of the blood pump system, at least one of the drive coupler and the pump are sterilizable.

20 In one embodiment of the blood pump system, the magnetic coupler of the blood pump can be coupled to one of the magnetic coupler of the motor and the first magnetic coupler of the drive coupler.

25 A still further aspect of the present invention involves providing a blood pump system. The blood pump system comprises a motor having a magnetic coupling, and a blood pump having a magnetic coupling. A drive coupler is provided having a power transmission member extending between a first magnetic coupling and a second magnetic coupling. The first magnetic coupling is for magnetically coupling with the magnetic coupling of the blood pump. The second magnetic coupling is for magnetically coupling with the magnetic coupling of the motor, whereby the blood pump may be remotely operated by the motor.

30 In one embodiment of the blood pump system, the blood pump is a centrifugal blood pump.

- 5 -

In one embodiment of the blood pump system, at least one of the first magnetic coupling and the second magnetic coupling is detachably coupled to the power transmission member.

5 In one embodiment of the blood pump system, at least one of the drive coupler and the pump are sterilizable.

Another aspect of the present invention involves providing a method of driving a sterile blood pump positioned within a sterile surgical field with a motor positioned outside the sterile surgical field. The method comprises the steps of: (a) positioning a sterile blood pump within a sterile surgical field; (b) positioning a non-sterile motor outside of the sterile surgical field; (c) providing a drive coupler having a drive element extending between a first magnetic coupling and a second magnetic coupling; (d) coupling the blood pump to the first magnetic coupling; (e) coupling the motor to the second magnetic coupling; and (f) operating the motor.

A further aspect of the present invention involves providing a drive coupler. The drive coupler comprises a drive element having a first end and a second end. A first magnetic coupling is attached to the first end of the drive element for coupling with a magnetic coupling of a blood pump. A second magnetic coupling is attached to the second end of the drive element for coupling with a magnetic coupling of a motor.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will now be described in greater detail with reference to the preferred embodiment illustrated in the accompanying drawings, in which like elements bear like reference numerals, and wherein:

FIG. 1 is a side view of a prior art blood pump connected to a known motor;

FIG. 2 is an exploded side view of the prior art blood pump disconnected from the known motor;

- 6 -

FIG. 3 is a side view of the blood pump, magnetic cable drive, and motor combination according to the present invention;

5 FIG. 4 is an exploded side view of the blood pump, magnetic cable drive, and motor combination of FIG. 3;

FIG. 5 is a side cross sectional view of the blood pump connected to one end of the magnetic cable drive; and

FIG. 6 is a side cross sectional view of the other end of the magnetic cable drive connected to the motor.

10 **DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS**

The blood pump system according to the present invention allows a blood pump 10 to be connected directly to a motor 12 in the conventional manner or positioned remote from the motor 12 and driven by a magnetic cable drive 20. The magnetic cable drive 20 is configured such that the same motor 12 can be used to drive the pump 10 whether the pump 10 is positioned directly on the motor 12 or connected to the motor 12 by the magnetic cable drive 20. When the system is used with the blood pump 10 positioned in the sterile surgical field, the magnetic cable drive 20 is connected to both the blood pump 10 and the motor 12 by easy connect magnetic couplings.

As shown in FIG. 3, the magnetic cable drive 20 of the present invention connects the blood pump 10 to the motor 12 and transmits rotation of a motor drive shaft (not shown) to an impeller (not shown) within the blood pump 10.

The magnetic cable drive 20 includes a female magnetic coupling 22 at one end and a male magnetic coupling 24 at an opposite end. Attached to the female and male magnetic couplings 22, 24 is a flexible drive shaft 26 which transmits rotation from one of the magnetic couplings to the other. The flexible drive shaft 26 is surrounded by a flexible casing 28.

As illustrated most clearly in the exploded view of FIG. 4, the blood pump 10 includes an annular flange 30

- 7 -

which is used to secure the pump 10 to the female magnetic coupling 22 or directly to the motor 12. The annular flange 30 preferably fits into a circular recess 32 in the female magnetic coupling 22 and is secured in place by
5 sliding the annular flange 30 beneath an L-shape tab 34 on one side of the magnetic coupling 22 and securing the blood pump 10 in place with a pivotable lever arm 36 which receives the annular flange 30. The male magnetic coupling 24 has an annular flange 40 which corresponds substantially
10 in shape and size with the annular flange 30 of the pump 10. The annular flange 40 of the male magnetic coupling 24 is configured to be received in a circular recess 42 in the motor 12 and secured in place by the fixed L-shaped tab 44 and pivotable lever arm 46.

15 As illustrated in FIG. 4, the magnetic couplings 22, 24 can be removable from the flexible drive shaft 26 and casing 28. The casing 28 may be secured to the magnetic couplings 22, 24 by a threaded member 50 on each of the couplings which is received in a threaded connector 52 of
20 the casing 28. The removable flexible drive shaft 26 and casing 28 allow the magnetic cable drive 20 to be converted to different lengths for use in different applications. Alternatively, the magnetic couplings 22, 24 may be permanently attached to the flexible drive shaft 26 and
25 casing 28.

The magnetic couplings 22, 24, the blood pump 10, and the motor 12 are shown in further detail in the side cross sectional views of FIGS. 5 and 6. As shown in FIG. 5, the blood pump 10 includes an impeller 56 having a plurality of
30 blades 58. The impeller 56 is secured to a rotatable drive shaft 60 by a nut 54. The impeller 56 is located within a hermetically sealed blood pump chamber 62. Blood leakage around the drive shaft 60 is prevented by a sealing member 64 positioned on a rear wall 74 of the blood chamber 62.
35 The drive shaft 60 is rotatably mounted in a base 66 of

- 8 -

the blood pump 10 by a bearing 68. A disk shaped member 70 is secured to the drive shaft 60 and is rotatable with the drive shaft 60. On the disk 70 are a plurality of magnets 72.

5 The female magnetic coupling 22 as illustrated in FIG. 5 includes a housing 76 containing a rotatable disk 78 having magnets 80 positioned on the disk 78. The disk 78 is fixed to a rotatable shaft 82 which is secured in the housing 76 by a bearing 84. The flexible drive shaft 26 is
10 inserted into the shaft 82 of the female magnetic coupling 22. The flexible drive shaft 26 and the shaft 82 of the magnetic coupling 22 are secured together in a non-rotatable connection which may be formed in a manner known in the art such as by inserting a square end of the
15 flexible drive shaft 26 into a square socket in the magnetic coupling shaft 82. As illustrated in FIG. 5, the magnetic coupling housing 76 and the rotatable coupling disk 78 each have a central recess for receiving a protruding portion of the pump 10.

20 FIG. 6 illustrates the connection of the male magnetic coupling member 24 to the motor 12. The male magnetic coupling member 24 includes a housing 88, a rotatable disk 90, and a rotatable shaft 92 secured to the disk 90. A plurality of magnets 94 are positioned within
25 the rotatable disk 90. The rotatable shaft 92 is mounted in the housing 88 for rotation by the bearings 96. The flexible drive shaft 26 is connected to the rotatable shaft 92 of the male magnetic coupling 24 in the same manner as described above with respect to the female magnetic
30 coupling 22. The male magnetic coupling 24 is removably received in the circular recess 42 in the motor 12 and secured in place by the fixed L-shaped tab 44 and pivotable lever arm 46. The motor 12 includes a drive shaft 100 connected to a rotatable disk 102 having a plurality of
35 magnets 104. The magnets 104 of the motor 12 are opposed

- 9 -

to the magnets 94 of the male magnetic coupling 24 such that rotation of the motor drive shaft 100 causes rotation of the rotatable shaft 92 of the male magnetic coupling 24.

5 In accordance with the present invention, the blood pump 10 can be removably attached either directly to the drive motor 12 or can be driven remotely by the magnetic cable drive 20 which is configured to connect the blood pump 10 to the motor 12. Preferably, the entire magnetic cable drive 20 is sterilizable, such as in an autoclave, 10 ETO, or the like, or is provided in a sterile condition and is disposable. Magnetic cable drive 20 may be provided in different lengths such as two feet, four feet, and six feet lengths to allow the motor 12 to be placed outside of the sterile surgical field while the sterilizable blood pump 10 15 is positioned close to the surgical site within the sterile surgical field.

Although the blood pump 10 according to the present invention has been described as having an axial inlet 14 and a tangential outlet 16, other configurations of the 20 pump are also possible. For example, the inlet and outlet may be coaxial. Further, the releasable connection between the blood pump 10 and the magnetic cable drive 20 or the motor 12 may be replaced by any known releasable coupling. The coupling may also allow the pump 10 and/or motor 12 to 25 rotate with respect to the magnetic cable drive 20.

According to one embodiment of the invention, the magnetic cable drive 20 may be connected to the motor 12 and/or the pump 10 at an angle and the connection may swivel. Thus, the pump 10 and motor 12 do not have to be 30 in perfect alignment.

While the invention has been described in detail with reference to the preferred embodiments thereof, it will be apparent to one skilled in the art that various changes and modifications can be made and equivalents employed, without 35 departing from the present invention.

- 10 -

WHAT IS CLAIMED IS:

1. A blood pump system, comprising:
a blood pump having an impeller for moving blood from an inlet to an outlet, and a magnetic coupler connected to said impeller;
5 a motor having a drive shaft and a magnetic coupler connected to said drive shaft, said magnetic coupler for magnetically driving said magnetic coupler of said blood pump; and
10 a drive coupler having a flexible power transmission member extending between a first magnetic coupler and a second magnetic coupler, said first magnetic coupler configured to be magnetically coupled to said magnetic coupler of said blood pump, and said second magnetic coupler configured to be magnetically coupled to said
15 magnetic coupler of said motor.
2. The blood pump system of Claim 1, including a latching system for connecting said pump to said motor such that said pump may be driven directly by said motor, said latching system also for connecting said pump to said drive
5 coupler such that said pump may be driven remotely from said motor.
3. The blood pump system of Claim 2, said latching system comprising an annular flange on said pump, an annular flange on said second magnetic coupler, engaging members on said first magnetic coupler for receiving said
5 annular flange on said pump, and engaging members on said motor for receiving one of said annular flange on said pump and said annular flange on said second magnetic coupler.
4. The blood pump system of Claim 3, wherein said engaging members on said first magnetic coupler and on said motor include a tab and a lever arm.
5. The blood pump system of Claim 1, wherein said flexible power transmission member is removably coupled to at least one of said first magnetic coupler and said second

- 11 -

magnetic coupler of said drive coupler.

6. The blood pump system of Claim 1, wherein at least one of said drive coupler and said pump are sterilizable.

7. The blood pump system of Claim 1, wherein said magnetic coupler of said blood pump can be coupled to one of said magnetic coupler of said motor and said first magnetic coupler of said drive coupler.

8. A blood pump system, comprising:

a motor having a magnetic coupling;

a blood pump having a magnetic coupling; and

5 a drive coupler having a power transmission member
extending between a first magnetic coupling and a second
magnetic coupling, said first magnetic coupling for
magnetically coupling to said magnetic coupling of said
blood pump, and said second magnetic coupling for
magnetically coupling to said magnetic coupling of said
10 motor, whereby said blood pump may be remotely operated by
said motor.

9. The blood pump system of Claim 8, wherein said blood pump is a centrifugal blood pump.

10. The blood pump system of Claim 8, wherein at least one of said first magnetic coupling and said second magnetic coupling is detachably coupled to said power transmission member.

11. The blood pump system of Claim 8, wherein at least one of said drive coupler and said pump are sterilizable.

12. A method of driving a sterile blood pump positioned within a sterile surgical field with a motor positioned outside the sterile surgical field, the method comprising the steps of:

5 positioning a sterile blood pump within a sterile surgical field;

positioning a non-sterile motor outside of said

- 12 -

sterile surgical field;

10 providing a drive coupler having a drive element
extending between a first magnetic coupling and a second
magnetic coupling;

coupling said blood pump to said first magnetic
coupling;

15 coupling said motor to said second magnetic coupling;
and

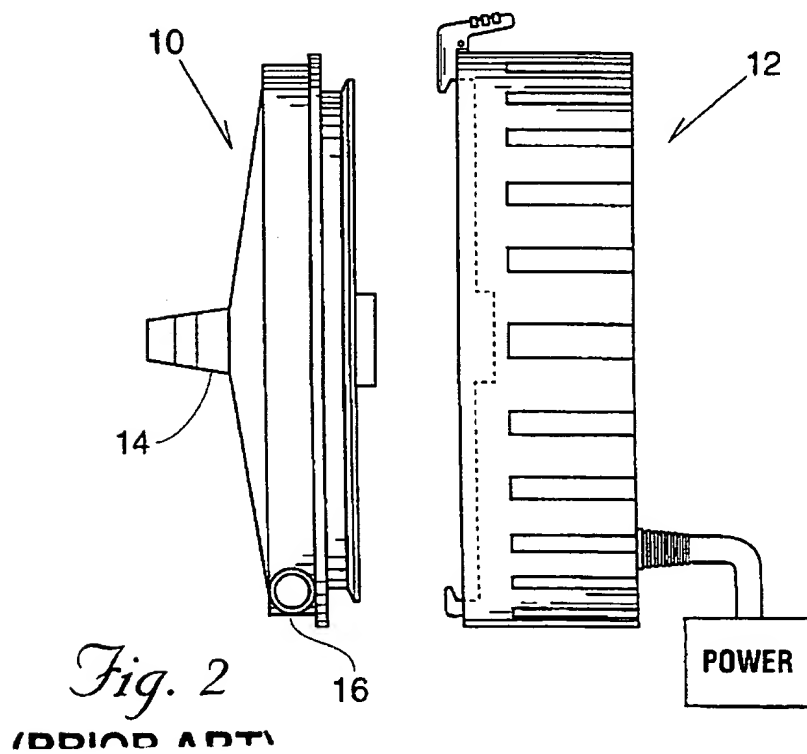
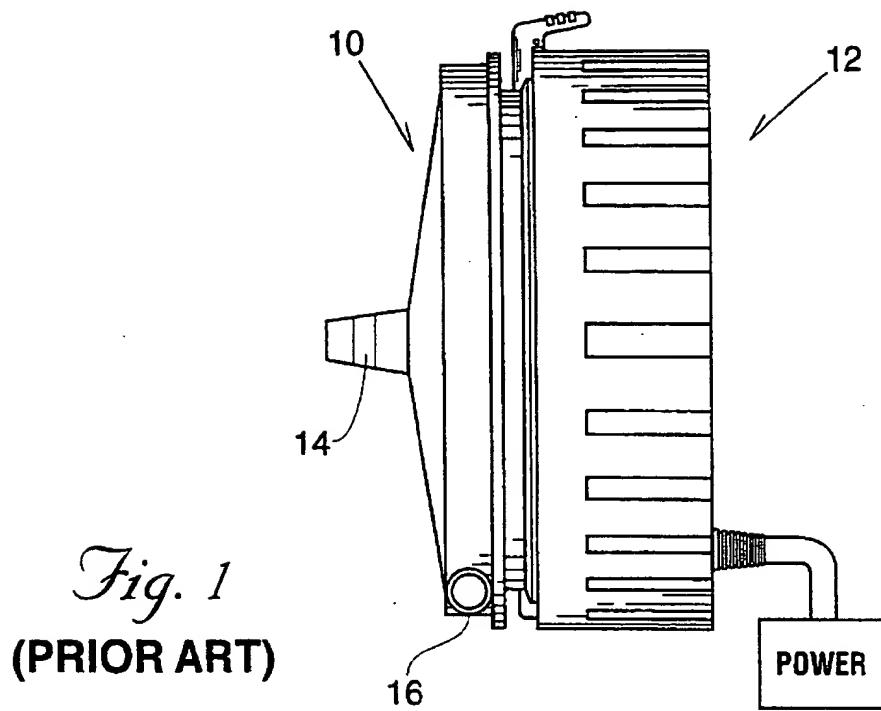
operating said motor.

13. A drive coupler, comprising:

a drive element having a first end and a second end;

5 a first magnetic coupling attached to said first end
of said drive element for coupling with a magnetic coupling
of a blood pump; and

a second magnetic coupling attached to said second
end of said drive element for coupling with a magnetic
coupling of a motor.



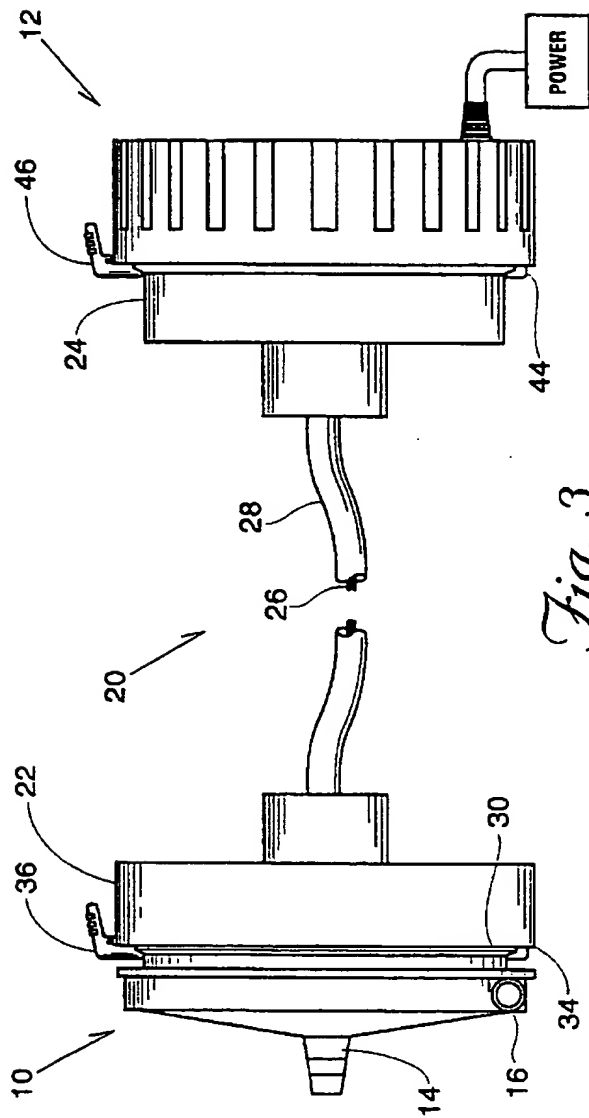


Fig. 3

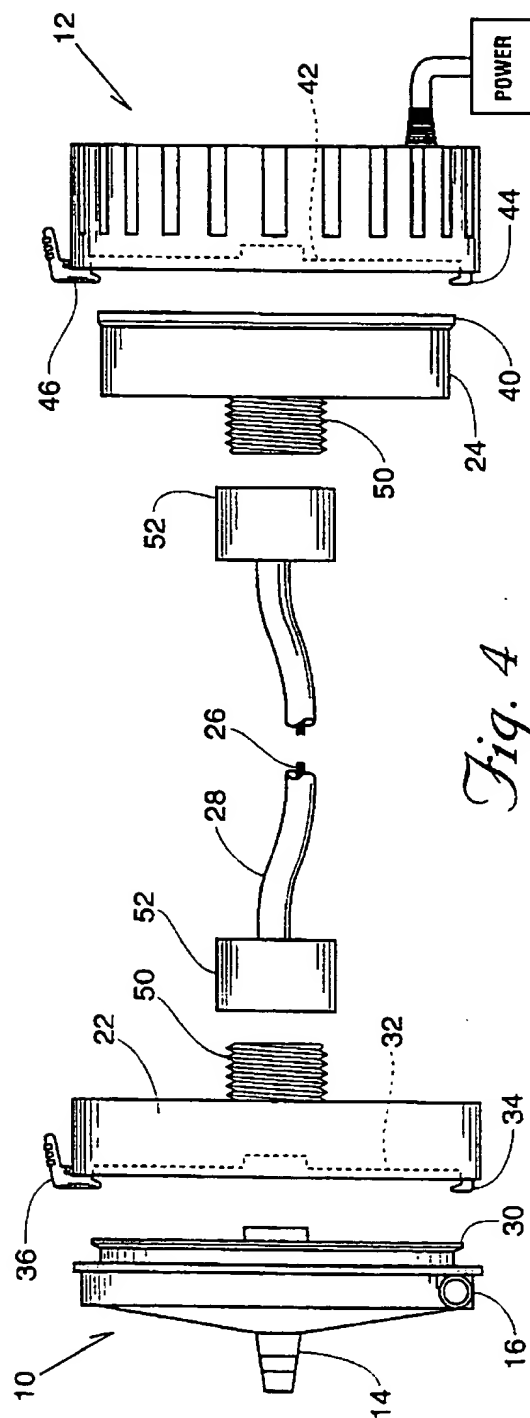
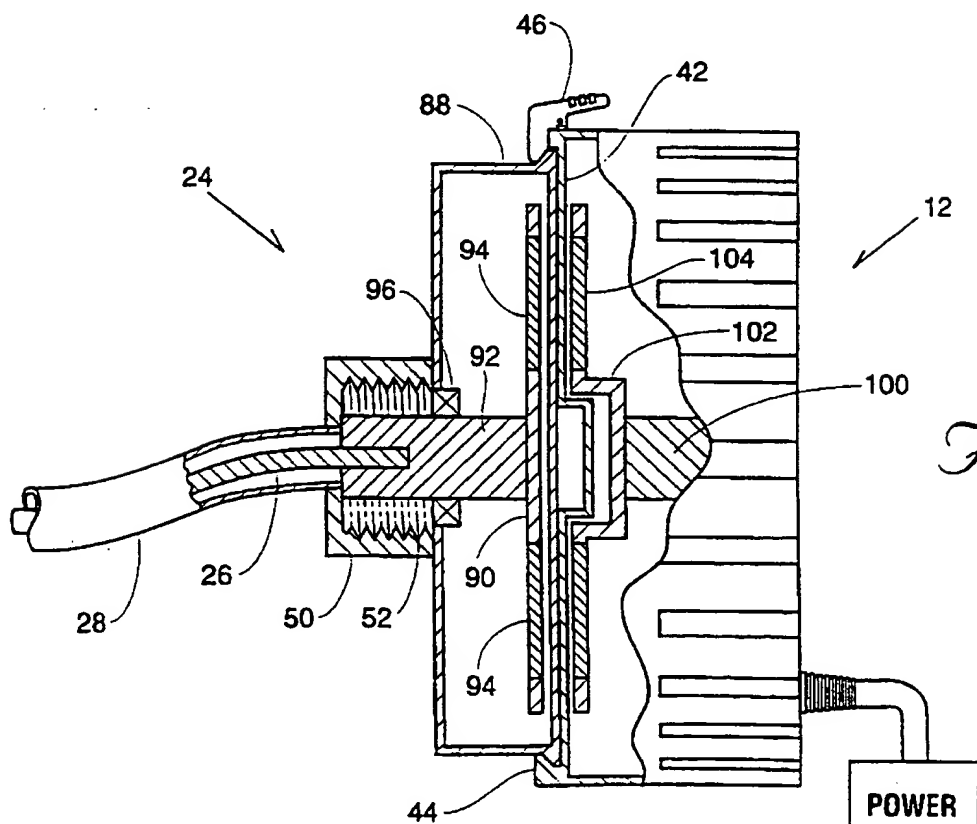
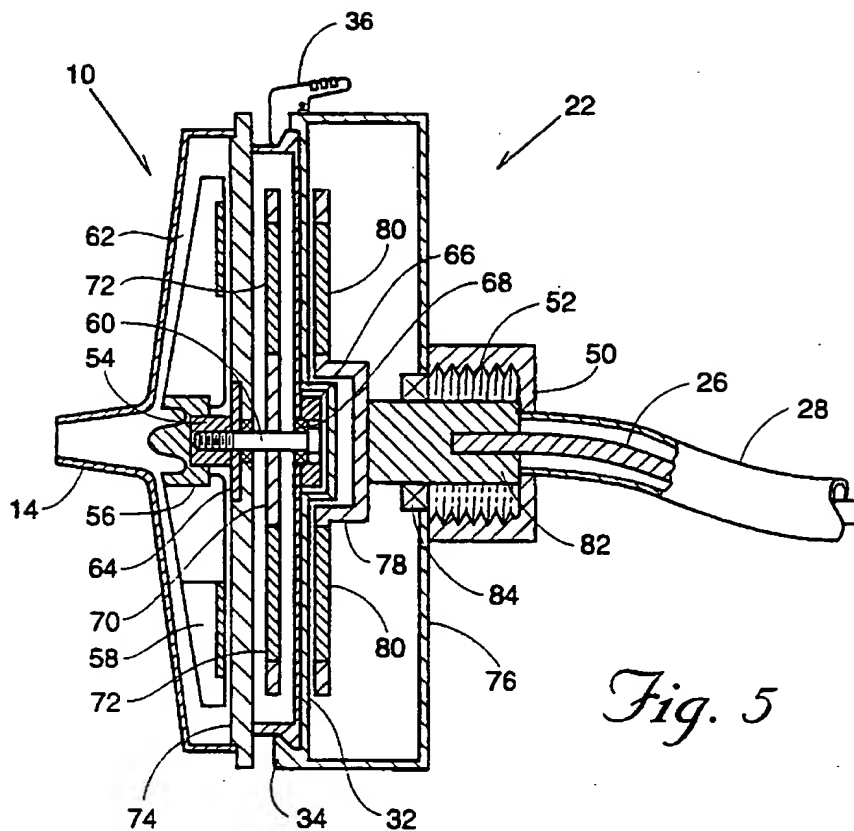


Fig. 4



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/22573

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : F04B 17/00

US CL : 417/420

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 417/420, 360, 423.1; 600/16, 17; 623/3; 604/131, 151, 500

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,147,186 A (BUCKHOLTZ) 15 September 1992, see entire document.	1-3 and 5-12
—		---
Y		4
Y	US 2,956,734 A (DOYLE) 18 October 1960, see Figs. 1 and 2.	4
A	US 5,021,048 A (BUCKHOLTZ) 04 June 1991, see entire document.	1

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:	*T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
A document defining the general state of the art which is not considered to be of particular relevance	*X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
B earlier document published on or after the international filing date	*Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	*Z* document member of the same patent family
O document referring to an oral disclosure, use, exhibition or other means	
P document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search

11 DECEMBER 1999

Date of mailing of the international search report

27 JAN 2000

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT

Authorized officer

John L. Th...